

COOPERATIVE AGREEMENT

UNIVERSITY OF WASHINGTON AND WASHINGTON STATE DEPARTMENT OF SOCIAL AND HEALTH SERVICES/ DEPARTMENT OF HEALTH

UW Assurance # M-1183

DSHS/DOH Assurance # M-1076

The officials having signed below commit their respective institutions to the following binding cooperative agreement with regard to reliance upon each others Institutional Review Boards (IRBs).

Unless a review by the relied upon IRB is denied in writing by either of the institutions:

Any time all of the human subjects, or their personal records, of a research activity will be identified or contacted for study recruitment through the non-public information or facilities of DSHS/DOH, the IRB of the DSHS/DOH will review for both participating institutions, except when the research activity is directly supported by a (non-DSHS/DOH) grant, contract, or cooperative agreement award to the UW, in which case review will be conducted by both IRBs.

Any time the research activity is sponsored by the DSHS/DOH, funded either directly with state funds or with federal pass-through funds, and subcontracted to the UW for the performance of the activity, the IRB of the DSHS/DOH will review for both participating institutions.

Any time the research activity is sponsored by the UW and conducted by a DSHS/DOH-affiliated investigator or co-investigator, and the human subjects, or their personal records, of the research activity will not be identified or contacted for study recruitment through the non-public information or facilities of DSHS/DOH, the IRB of the UW will review for both participating institutions.

These procedures apply to both expedited and full board reviews of research covered by this agreement. Each institution reserves the right to insist on review by its own IRB regardless of this agreement, so long as that preference is in writing and provided to the administrators of both IRBs.

IRB reviews shall occur with voting membership and/or consultation supplementation appropriate to any given activity. Changes in voting membership shall be reported to the Office for Protection from Research Risks (OPRR) as they occur.

The cooperating institutions agree that the reviewing IRB shall be adequately supported in its function, cooperate with reporting requirements and requests for additional information, and abide with IRB decisions.

Disapprovals may not be administratively overruled by either cooperating institution. Relevant minutes of IRB meetings, and/or copies of IRB correspondence to investigators, shall be made available to both cooperating institutions, upon request.

This agreement will be continuous, but may be terminated by either party upon submission of written notice to the administrators of both IRBs at least 90 days in advance of the effective termination date.

DEFINITIONS

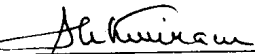
"Sponsored" means the institution takes primary responsibility for the conduct of the research activity and assumes ultimate liability if something goes wrong.

"Funded" means the research activity is supported by a grant, contract or cooperative agreement award from the federal government, private or public foundation, or proprietary sponsor, to the institution. The term does not apply to a research activity that is supported by a subcontract from DSHS/DOH to the university.

"Investigator's affiliation" refers to the agency that employs the investigator; some investigators have multiple affiliations, but their principal employment always should be with only one institution.

"DSHS/DOH subjects/records/facilities" means that human subjects, or their personal records, are identified or contacted through the non-public information or facilities of DSHS/DOH, or that the research is conducted within a DSHS facility.

AUTHORIZED INSTITUTIONAL OFFICIALS

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Date: 11-4-97

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Date: August 22, 1997

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Date: 8/26/97

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Only for OPRR Use

DHHS APPROVING OFFICIAL

Signature: Kamal K. Mittal

Date: 3/16/98

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